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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/695,577	10/28/2003	Edwin Raymond Chapman	960296-99004	8039

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EXAMINER	
FORD, VANESSA L	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 12/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/695,577	CHAPMAN ET AL.	
	Examiner	Art Unit	
	Vanessa L. Ford	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 September 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-14 and 41-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-14 and 41-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/19/04&7/22/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election with traverse of Group II, claims 10-14 and further species election of SEQ ID NO:7 filed on September 6, 2005 is acknowledged. Applicant has made elections in response to the restriction requirement with traverse. Applicant urges that restriction is optional in all cases. Applicant urges that Groups I-V can be examined without serious search burden to the Examiner. Applicant urges that according to the MPEP section 803.04, ten independent and distinct nucleotide sequences will be examined in a single application without restriction. Applicant asserts that they believe that the same applies to amino acid sequences. Applicant urges that SEQ ID NOs: 7 and 9 should be examined together.

Applicant's arguments filed September 6, 2005 have been fully considered but they are not persuasive. These arguments have been fully considered but are not found to be persuasive for the reasons below:

First, the classification system has no statutory recognition whether inventions are independent and distinct. For example, each class and subclass is comprised of numerous completely independent and distinct patented inventions.

Second, MPEP 803 states that restriction is proper between patentably distinct inventions where the inventions are (1) independent or distinct as claimed and (2) a serious search and examination burden is placed on the examiner if restriction is not required.

The term "distinct" is defined to mean that two or more subjects as disclosed are related, for example as product and method of use, etc., but are capable of separate

manufacture, use or sale as claimed, and are patentable over each other (see MPEP 802.01). In the instant situation, the inventions of Groups I-V are drawn to distinct inventions which are separate products and methods capable of separate manufacture, use or sale as described in the previous Office Action.

Classification of the subject matter is merely one indication of the burdensome nature of the search. The literature search, particularly relevant in this art, is not co-extensive, because for example, Groups I, II and II is drawn to structurally and functionally different products. Groups I and V are drawn to different methods which require different method steps, parameters and endpoints. Clearly different searches and issues are involved in the examination of each Group.

To address Applicant's comments regarding the examination of multiple sequences, it should be noted that the MPEP at section 803 states:

> "Accordingly, in most cases, up to ten independent and distinct nucleotide sequences will be examined in a single application without restriction. In addition to the specifically selected sequences, those sequences which are patentably indistinct from the selected sequences will also be examined. Furthermore, nucleotide sequences encoding the same protein are not considered to be independent and distinct inventions and will continue to be examined together".

However, upon further review, SEQ ID NOs:: 7 and 9 will be examined together.

For these reasons the restriction requirement is deemed to be proper and is therefore made FINAL. Claims 1-9 and 15-40 have been cancelled. Claims 41-50 have been added.

Specification Objection

2. The specification is objected to for the following informality: At page 19, last sentence on the page should end in a period (.). Correction is required.

Claim Objection

3. Claims 10-14 and 41-50 are objected to for the following informality: "BoNT/B" should be changed to "botulinum toxin serotype B" in the first occurrence in the claims. Correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 10-14 and 41-50 are rejected under 35 USC 112 second paragraph for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 10 recites "...an amino acid...". It is unclear as to what Applicant is referring. Does Applicant intend that "an amino acid" is a subset of the amino acid sequence that is homologous or at least 70% identical to the murine synaptotagmin II BoNT/B binding domain ...". Clarification and/or correction is required.

5. Claim 43 is rejected under 35 USC 112 second paragraph for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 43 recites "...luminal portion of a synaptotagmin...". It is unclear as to what Applicant intends. Clarification and/or correction is required.

6. Claim 45 is rejected under 35 USC 112 second paragraph for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 45 depends from claim 10 and recites "...wherein the ligand is an antibody or a botulinum toxin fragment...". Claim 10 recites "...with the proviso that where the polypeptide is full-length synaptotagmin, the ligand is not a botulinum toxin. It is unclear as to what Applicant is referring since claim 10 does not include a botulinum toxin component. Clarification and/or correction is required.

7. Claim 47 is rejected under 35 USC 112 second paragraph for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 47 recites " ...wherein the polypeptide is located *in vivo*. If Applicant intends that the polypeptide is *in vivo* then the ligand is also in vivo since the polypeptide is in a complex with the ligand. It is unclear as to whether Applicant is claiming an organism (e.g. rat, mouse or human) since the claim recites that the polypeptide is *in vivo*. Clarification and/or correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 10-14 and 41-50 are rejected under 35 U.S.C. 102(a) as anticipated by Nishiki et al *(FEBS Letters 378, 1996, p. 251-257)*.

Claims 10-14 and 41-50 are drawn to a complex of a ligand and a polypeptide wherein the polypeptide comprises an amino acid sequence that is homologous or at least 70% identical to a murine synaptotagmin II BoNT/B binding domain at amino acid position 40 to 60 and wherein the ligand binds to the polypeptide at the amino acid 0sequence that is homologous or at least 70% identical the murine synaptotagmin II BoNT/B binding domain at amino acid position 40 to 60 with the *proviso* that where the polypeptide is a full length synaptotagmin the ligand is not a botulinum toxin.

Nishiki et al teach a complex comprising synaptotagmin II and gangliosides (page 255, figure 3). Nishiki et al teach that the synaptotagmins used in the complex were recombinant synaptotagmins (page 253). The claim limitation "wherein the polypeptide has a sequence identical or homologous to a luminal portion of a synaptotagmin would be inherent in the teachings of the prior art. The claim limitation "wherein the polypeptide comprises an amino acid sequence that is homologous or at least 70% identical to a murine synaptotagmin II BoNT/B binding domain at amino acid position 40 to 60 and wherein the ligand binds to the polypeptide at the amino acid

sequence that is homologous or at least 70% identical the murine synaptotagmin II BoNT/B binding domain at amino acid position 40 to 60" would be taught by the prior art since the prior art teaches murine synaptotagmin II (page 253). The claim limitation "wherein ligand reduces binding of botulinum neurotoxin B to the polypeptide is being viewed as a limitation of intended use. Nishiki et al anticipate the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's complex with the complex of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the complex of the prior art does not possess the same material structural and functional characteristics of the claimed complex). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

9. Claims 10-14 and 41-50 are rejected under 35 U.S.C. 102(a) as anticipated by Nishiki et al *(The Journal of biological Chemistry, Vol. 269,No. 14, pp. 10498-10503).*

Claims 10-14 and 41-50 are drawn to a complex of a ligand and a polypeptide wherein the polypeptide comprises an amino acid sequence that is homologous or at least 70% identical to a murine synaptotagmin II BoNT/B binding domain at amino acid position 40 to 60 and wherein the ligand binds to the polypeptide at the amino acid sequence that is homologous or at least 70% identical the murine synaptotagmin II BoNT/B binding domain at amino acid position 40 to 60 with the proviso that where the polypeptide is a full length synaptotagmin the ligand is not a botulinum toxin.

Nishiki et al teach a complex comprising synaptotagmin and gangliosides (page 10502, 2nd column). Nishiki et al teach that the synaptotagmins used in the complex were recombinant synaptotagmins (page 10500). The claim limitation "wherein the polypeptide has a sequence identical or homologous to a luminal portion of a synaptotagmin would be inherent in the teachings of the prior art. The claim limitation "wherein the polypeptide comprises an amino acid sequence that is homologous or at least 70% identical to a murine synaptotagmin II BoNT/B binding domain at amino acid position 40 to 60 and wherein the ligand binds to the polypeptide at the amino acid sequence that is homologous or at least 70% identical the murine synaptotagmin II BoNT/B binding domain at amino acid position 40 to 60" would be taught by the prior art since the prior art teaches rat synaptotagmin (page 10500). The claim limitation "wherein ligand reduces binding of botulinum neurotoxin B to the polypeptide is being viewed as a limitation of intended use. Nishiki et al anticipate the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's complex with the complex of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the complex of the prior art does not possess the same material structural and functional characteristics of the claimed complex). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Status of Claims

10. No claims allowed.

Conclusion

11. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308–0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 872-9306.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (571) 272-0857. The examiner can normally be reached on Monday – Friday from 9:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (571) 272-0864.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov./>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vanessa L. Ford
Biotechnology Patent Examiner
November 26, 2005

NITA MINNIFIELD
PRIMARY EXAMINER
11/28/05